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Kieran P. J. Murphy

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EXAMINER

ARAJ, MICHAEL J

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/594,685
Filing Date: June 16, 2000
Appellant(s): MURPHY, KIERAN P. J.

MAILED
MAR 26 2007
Group 3700

Raymond W. Green
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed August 22, 2005 appealing from the Office action mailed November 15, 2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. The after final amendments filed on February 10, 2005 were not entered. A petition filed on May 9, 2005 under 37 CFR 1.181 to review the denial for entry of the amendment after final filed on February 10, 2005 was dismissed. The examiner's position was deemed appropriate and proper.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,128,173	LAZARUS ET AL.	12-1978
6,158,437	VAGLEY	12-2000
5,847,046	JIANG ET AL.	12-1998
5,817,074	RACZ	10-1998
5,690,618	SMITH ET AL.	11-1997
5,626,230	SHANLEY ET AL.	5-1997
5,506,257	MACLEOD ET AL.	4-1996
5,240,415	HAYNIE	8-1993
5,147,308	SINGER	9-1992
5,084,043	HERTZMANN ET AL.	1-1992
4,554,686	BAKER	11-1985
3,910,273	ARLERS	10-1975

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 22, line 1, "wherein the vertebroplasty injection components comprise: a vertebroplasty needle", is indefinite because it is unclear if the components are a combination of all the components, in combination, of the first and second tray, or if each tray, i.e. first and second, includes the components listed in claim 22.

Claim 23 has a problem similar to the one of claim 22.

It is noted that for examination purposes claim 22, would be considered as each tray including all the components listed in claim 22. Claim 23 would be considered in a similar fashion, e.g. each tray including all the components listed in claim 23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarus, et al.

Lazarus, et al. disclose a kit 10 comprising a first tray 10a of components and a second tray 10b of components. The first and second tray are individually assembled and packaged and are kept sterile until use.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9).

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive." (see col. 3, lines 5-10). Thus, it would have been obvious to one skill in the art at the

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time the invention was made to place specific tools, such as local anesthesia, anesthesia aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

Claims 1-16, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vagley (U.S. Patent No. 6,158,437 cited on PTO-892, paper no. 9) and Shanley, et al.; Macleod, et al.; Smith, et al.; Arlers; Racz; Jiang, et al.; Singer; Draenert; Haynie; Hertzman, et al.; and Baker are cited as evidence.

Vagley discloses a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67). Vagley further discloses that the tray can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward enhanced efficiency in the surgical site and more accurate and prompt delivery of the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive." (see col. 3, lines 5-10). Shanley, et al. disclose that kits or tray can include a local anesthesia injection needle 6. Macleod, et al. disclose that kits or tray can include a

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local anesthesia compound. Smith, et al. disclose a aspiration syringe for fluids (see col. 9, lines 9-11). Arlers discloses another aspiration syringe. Racz discloses an aspiration needle for fluids. Jiang, et al. disclose that liquid monomers can be on a kit or tray. Singer discloses another aspiration needle. Draenert discloses a mixing bowl and polymeric powder. Haynie discloses that a tray or kit can have a mixing spatula. Hertzman, et al. disclose that a tray or kit can include a scalpel. Baker discloses that a tray or kit can include opacifier. Thus, it would have been obvious to one skill in the art at the time the invention was made to place specific tools, such as local anesthesia, anesthesia aspiration syringe; anesthesia aspiration needle; anesthesia injection needle; liquid monomer; monomer aspiration needle; monomer aspiration syringe; mixing bowl; mixing spatula; polymer powder; opacifier; scalpel; vertebroplasty needle, etc., need in a tray to cater to the preference of a specific surgeon during a specific procedure.

(10) Response to Argument

(a) The Rejection of Claims 22 and 23 as Indefinite

The amendments filed on February 5, 2005 were denied entry and affirmed by the directors of Technology Center 3700. Therefore with the currently standing claims filed on July 7, 2004, the claims remain unclear if the claims recited components that were present collectively in both trays, or if each (the first and second) tray contained the recited components. Claims 22 and 23 remain indefinite.

(b) The Rejection of Claims 17-19 as Anticipated by Lazarus

In response to applicant's argument that Lazarus does not have vertebroplasty injection components in either tray, it is noted that Lazarus's tray 10b includes a syringe 36 and needle 38 and they are capable of being used in a spinal surgical procedure, e.g. for injecting anesthesia. Lazarus's tray 10a includes a cannula for injecting and/or aspirating fluid and it is capable of being used in a spinal surgical procedure, e.g. for injecting or aspirating nucleus pulposus. Thus, it is clear that each tray includes an injection component and they can perform a function in spinal surgery if one so desires.

Furthermore, with regard to the functional language "vertebroplasty", it is noted the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

In response to the Declaration filed on July 27, 2004 under 37 CFR 1.132, it is noted that the Declaration is insufficient to overcome the rejection of claims 1-21 based as set forth in the last Office action and this Office action because: the declaration is directed to an opinion from applicant and not to evidence. It is noted that in assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established (i.e. the ability of the different components to perform a function), the strength of any opposing evidence (i.e. no "evidence" has been presented with the declaration), the interest of the expert in the outcome of the case (i.e. the expert which in this case is the applicant has a 100 percent interest in the outcome of the case), and the presence or absence of factual support for the expert's opinion (i.e. no facts are presented to support the expert's opinion). *Ashland Oil, Inc. v. Delta Resins &*

Refractories, Inc., 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). Factually based expert opinions on the level of ordinary skill in the art are sufficient to rebut the prima facie case of obviousness. *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978). In the Declaration filed on July 27, 2004, no "facts" are present to support applicant's opinion. It is noted that "facts" are events, acts or occurrences which have actually taken place. Thus, the Declaration has been considered, however, it is not persuasive to overcome the art of record.

Furthermore, the examiner would like to point out another example of why the Declaration is not persuasive. For example, in the Declaration filed on July 24, 2004, the expert, i.e. the applicant of the current application, states that the Lazarus's syringe and needle are "**NOT**" vertebroplasty injection components, but the expert agrees that the Lazarus's syringe and needle are capable of injecting anesthetic, including doing so into the spine, and that theses are general surgical apparatuses rather than vertebroplasty injection components. However, in applicants specification and claims, a local anaesthesia injection needle, which according to the declaration is a "general surgical apparatus", is considered a vertebroplasty injection components (see for example claim 22). Thus, clearly applicant is contradicting himself.

Also, in response to applicant's argument in the declaration about that Lazarus's and bone-cement injection needles, the limitations on which the Applicant relies (i.e., bone-cement injection needles) are not stated in the claims 17-19. Therefore, it is irrelevant whether the reference includes those features or not.

In response to applicant's argument in the declaration that the Lazarus's cannula is not a vertebroplasty injection component, it is noted that the cannula clearly, if one so desired, has the ability to perform the function of injection or aspirate as an injection or aspiration needle. Furthermore, **it is noted the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).** In the current case Lazarus's clearly has the structure recited in the claims, i.e. a first tray of components, a second tray of components and the first and second trays are individually assembled and packaged and kept sterile until use.

Furthermore, the declaration filed by applicant did not provide any evidence to prove that the structure of the device of Lazarus is incapable of performing the functions.

In response to applicant's argument about claim 17 and the recitation of "performing a first vertebroplasty injection through a first pedicle of a vertebral body" and "performing a second vertebroplasty injection through a second pedicle of said vertebral body" in the declaration, it is noted that claim 17 is an apparatus claim and not a method claim. Furthermore, it is noted that the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). The manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. **Ex parte Masham, 2 USPQ2d 1647 (1987).**

(c) The Rejections of Claims 1-16, 20 and 21 as Obvious from Vagley or from Vagley in View of Eleven Other References

In response to applicant's argument that the Examiner has used Applicant's claims as a shopping list to find a patent that teaches each element in the combination, but has not cited or applied a reference that teaches the *combination* itself, it is noted that applicant's argument states that the applicant's claims are cited in combination but has not been cited or applied a reference that teaches or suggest the combination itself. However, the examiner would like to point out that the rejections to the claims which include a "shopping list", as stated by applicant, are obviousness type of rejection not an anticipation rejection, thus if the examiner would have found the "*combination*" of elements itself, he would have done a 35 U.S.C. 102, anticipation rejection.

In response to applicant's argument in the declaration that Vagley disclose a rhinoplasty kit for plastic surgery and that none of the Vagley's components can be used for vertebroplasty, it is noted that in a piecemeal analysis of the reference, one cannot show non-obviousness by attacking references individually where, as here, the rejections are based on combinations of references. Furthermore, the examiner would like to point out that Vagley not only discloses a rhinoplasty kit. He further has a method of performing a surgical procedure wherein an instrument support tray is provided having a plurality of surgical instruments positioned thereon (see col. 1, lines 65-67) and he further discloses that the tray **can be customized to cater to the preference of a specific surgeon during a specific procedure and in such case may also provide additional equipment preferences of the surgeon. All this is directed toward**

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enhanced efficiency in the surgical site and more accurate and prompt delivery the correct instrument to the surgeon (see col. 5, lines 40-50). Vagley define a surgical procedure as "a procedure performed on a patient by a physician, dentist, veterinarian or other legally authorized health care professional which procedure involves a plurality of hand-held instruments and is at least partially invasive" (see col. 3, lines 5-10). This shows support that there is a teaching or suggestion of the particular combinations of the cited references.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

 Michael Araj

Conferees:

Eduardo Robert 

Angela Sykes 